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IV-D-105



ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

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RENEE CIPRIANO, DIRECTOR

217-782-3397

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U. S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

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Requested 7000 1670 008 6137 1515

Re: Docket No. EC-2000-007
Establishment of Electronic Reporting: Electronic Records; Proposed Rule
66 Fed. Reg. 46161 (August 31, 2001)

Ladies and Gentlemen:

The Illinois Environmental Protection Agency (Illinois EPA) would like to thank you for this opportunity to comment on the proposed rule to allow electronic reporting and record-keeping published at 66 Fed. Reg. 46161 (August 31, 2001). Our comments on the proposal are attached. They are organized according to the preamble provisions to which they respond.

Illinois EPA welcomes efforts by the United States Environmental Protection Agency (USEPA) to promote the advancement to electronic reporting by preparing the needed regulatory and procedural foundation. Illinois EPA has participated extensively, along with numerous other States, the National Governors' Association (NGA) and the Environmental Council of States (ECOS), to offer input on development of an appropriate electronic reporting policy. This participation has included our representation on the State Electronic Commerce and Electronic Data Interchange Steering Committee (SEES) that led to publication of "A State Guide for Electronic Reporting of Environmental Data". Efforts have uniformly focused on establishing a performance-based policy that is technology-neutral, so as to allow flexibility to adopt ongoing technological advancements that prove to be beneficial. While Illinois EPA is supportive of many aspects of USEPA's proposed rule, we do have a number of concerns about the stated electronic reporting and record-keeping requirements as specifically addressed in the attached comments.

If you have any questions regarding these comments, please contact Bruce Carlson at (217) 782-5544 or at the above address.

Sincerely,

Renee Cipriano
Director

GEORGE H. RYAN, GOVERNOR

**COMMENTS OF THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
REGARDING THE PROPOSED RULE FOR ESTABLISHMENT OF
ELECTRONIC REPORTING; ELECTRONIC RECORDS PUBLISHED AT
66 FED. REG. 46161 (AUGUST 31, 2001)**

I. Overview

B. What Will the Proposed Regulations Do? - p. 46164

Issue - The United States Environmental Protection Agency ("USEPA") is proposing to require that State, tribal and local programs for electronic reporting first receive USEPA approval to assure that they meet the requirements for reporting systems set forth in this rule. This requirement would apply to all "authorized State, tribal or local environmental programs" which is broadly defined in the proposed language of 40 CFR 3.3 to mean environmental programs which USEPA has "approved, authorized, or delegated to a State, tribe or local government to administer under a federal environmental program". The preamble to the proposed rule goes on to describe programs that are "approved, authorized, or delegated" as including not only federal environmental programs administered on USEPA's behalf, but also state environmental programs that are administered "in lieu of the federal regulatory program in that State".

Comment - USEPA review and approval of State electronic reporting programs should be required only with regard to environmental programs for which primacy to administer that program has been formally delegated to the State. Encompassing within the scope of the electronic reporting rule those environmental programs that States are said to administer "in lieu of the federal regulatory program" could be very broadly interpreted to include many of the environmental programs States presently carry out that are only tangentially related to federal environmental statutes. For example, State administered site remediation programs dealing with contaminated sites not listed on the National Priorities List could be covered, as well as groundwater protection programs developed under State statutes and nonhazardous waste treatment, storage and disposal programs.

III. Scope of Today's Proposal

C. Which Documents Could be Filed Electronically? - p. 46167

Issue - USEPA requested comments and advice on priorities for electronic reporting implementation.

Comment - The Illinois Environmental Protection Agency ("Illinois EPA") would recommend that first priority be given to implementation of electronic reporting for Discharge Monitoring Reports ("DMRs") submitted pursuant to the Clean Water Act's requirements for the National Pollutant Discharge Elimination System ("NPDES") permit program. NPDES permits typically require monthly reporting of self monitoring data by the permittee on standardized forms. The permittees include all direct dischargers of pollutants to navigable waters and cover a broad spectrum of large and small facilities from industrial manufacturers to publicly owned wastewater treatment works.

In Illinois, there are approximately 2,600 active NPDES permits resulting in the submission of around 3,500 paper DMR forms to the Illinois EPA each month. In February of 2001, Illinois EPA sent a survey to 1,841 NPDES permittees in order to determine their degree of interest in submitting DMRs electronically and to assess their overall readiness for participation in electronic reporting. A total of 1,109 survey responses were received, amounting to a response rate of greater than 60 percent. The survey revealed that 78 percent of the respondents were interested or very interested in submitting DMRs electronically. Since Illinois EPA is contemplating development of a system for direct submission of DMR data over the Internet, using a Web-based interface, digital signatures and an extensible markup language ("XML") format, questions were also asked about the respondents' available computer hardware, software and Internet connectivity. An analysis of the survey responses showed that 89 percent of the respondents already had the requisite level of hardware, software and connectivity needed to support the anticipated Web-based electronic reporting system.

Applying electronic reporting to submission of DMRs would be a logical first priority. It would involve participation by a large, diverse community of permittees who currently submit paper reports on a regular monthly basis. The data from these DMRs currently needs to be manually entered into the federal Permit Compliance System ("PCS") database. Use of electronic reporting for this application would improve the timeliness and accessibility of the monitoring data, as well as avoiding the cost and potential inaccuracy associated with having to re-key from paper reports.

IV. The Requirements in Today's Proposal

B. What Requirements Must Electronically Maintained Records Satisfy? - p. 46170

2. EPA's Proposed Criteria for Electronic Record-Retention Systems

Issue - USEPA sets forth a set of 9 criteria for electronic record-retention systems said to be necessary in order for electronic records to be trustworthy and reliable. Among those criteria are a required capability to produce copies of electronic records in both human readable and electronic form; use of secure, computer-generated, time-stamped audit trails; and making computer systems (including hardware and software), controls and documentation readily

available for USEPA inspection. An issue that appears to need further consideration and clarification is the scope of electronic record-retention systems subject to requirements set forth in those criteria.

Comment - As defined in Section 3.3 of the proposed rule, an “electronic record-retention system” refer to “any set of apparatus, procedures, software, records or documentation used to retain exact electronic copies of electronic records and electronic documents”. While an “electronic document” has a narrow definition that appears appropriate for this electronic reporting rule, “electronic record” is defined much more broadly. An electronic document refers to a document submitted as an electronic record and communicated via a telecommunications network, but specifically excludes facsimiles and documents submitted on such magnetic media as diskettes, compact disks or tapes. In contrast, electronic record refers to any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. The problem with application of these definitions is that the requirements for electronic record-retention systems can be interpreted to apply to a much wider scope of electronic information than simply the electronic documents that are reported directly to the environmental agency. Electronic records could include any of the supporting analyses or other supporting information from which the electronic documents are prepared, if such analyses or information are maintained in digital form. It could even include the maintenance of magnetic media by environmental agencies or submitters, since the exclusion set forth for electronic documents is not present in the electronic records definition and the electronic record-retention system requirements apply to both electronic documents and electronic records. The Illinois EPA believes that electronic recordkeeping requirements for electronic records and electronic record-retention systems should be limited in scope to apply only to the electronic documents that are actually submitted to an environmental agency under a federal environmental program.

4. The Relation of These Requirements to Food and Drug Administration (FDA) Criteria

Issue - USEPA states that the proposed rule is intended to be consistent with criteria set forth for electronic document systems in other relevant regulations, such as the Food and Drug Administration’s (“FDA”) in 21 CFR part 11. USEPA asks whether the proposed rule achieves that consistency and whether such consistency is an appropriate goal for the rulemaking. Further, USEPA is said to be considering whether or not to include additional provisions found in the FDA regulations in the final rule.

Comment - The Illinois EPA believes that it is important for USEPA to keep in mind the diversity of submitters who would potentially make use of electronic reporting to provide environmental data to USEPA and state environmental agencies, as compared with submitters subject to reporting requirements of the FDA regulations. In contrast to the FDA regulations, which tend to primarily impact the pharmaceutical industry, USEPA’s electronic

reporting requirements would impact a wide range of large and small manufacturers, businesses, and governmental entities including numerous small municipalities. While there appears to be general consistency between the requirements of USEPA's proposed rule and those of the FDA regulations, any decision to incorporate additional provisions from the FDA regulations should take into account whether those provisions would add cost or complexity to the burden imposed on those who would electronically submit environmental data. The regulated community under the FDA regulations would seem to be in a better position to handle more costly or complex requirements than would the diverse regulated community subject to USEPA's proposed rule.

C. What is the Process That EPA Will Use To Approve Changes To Authorized State and Tribal Programs Related to Electronic Reporting and Record-Keeping? - p. 46171

Issue - In describing the process that States would need to complete in order to obtain approval for their electronic reporting and record-keeping programs, USEPA explains that a State planning to institute electronic reporting for an authorized program will have to meet the normal USEPA approval requirements for that particular program, whether the approval is being sought for a single program or for "an electronic document receiving system that would support multiple, authorized, delegated, or approved environmental programs". In cases where multiple programs will be affected, USEPA points out that approval will have to be sought individually for electronic reporting under each such program, although USEPA indicates that it would expect to evaluate these simultaneously submitted applications from a State in a single internal review. USEPA also expressly solicits comments on whether another approach should be taken to State program modification or revision for electronic reporting or record-keeping.

Comment - As previously explained, Illinois EPA takes the position that USEPA review and approval of State electronic reporting programs should be required only with regard to environmental programs for which primacy to administer that program has been formally delegated to the State. Furthermore, the requirement in the proposed rule for utilizing a full, formal program delegation agreement amendment process as the means for review and approval of a State system for electronic reporting is overly cumbersome and excessively time consuming. Since the essential requirements for such substantive matters as the content of reports, frequency of reporting, use of signed certifications, and period of record retention would remain unchanged under an electronic reporting system, USEPA could appropriately conduct its review and approval of State systems by a more informal route or, ideally, States could be allowed to self certify their compliance with the system requirements developed by USEPA. Having to seek system approval separately for electronic reporting under each particular federal program is a further burden on the States that is unnecessary. In most cases, the electronic reporting system developed by a State would be used to receive reports with regard to multiple federal programs and only the layout and content of the submission form itself would vary from program to program. Consequently, a State should readily be

able to apply for system approval covering multiple programs in a single application or certification to USEPA.

D. What Criteria Are EPA Proposing That State Electronic Report Receiving Systems Must Satisfy? - p. 46171

3. Submitter Registration Process

Issue - In the preamble to the proposed rule, USEPA sets forth contemplated language for a series of agreements and renewal statements that would need to be signed by those submitting electronic reports. Although USEPA is not currently proposing to codify the specific language for these agreements and renewal statements in the rule, USEPA seeks comments on all of the proposed registration agreement and renewal statement provisions, including the proposed provisions for administrative determination of the frequency and terms of the renewal agreements. USEPA also seeks comments on whether all or any of these agreements and statements should be signed on paper, as well as whether an additional certification statement should be required to be signed when the signature holder surrenders the signature for whatever reason (such as a change in jobs or retirement).

Comment - In most electronic reporting systems, including those presently contemplated by Illinois EPA, the electronic signature affixed to documents requiring such signature will be handled by means of a digital signature managed as part of a public key infrastructure (PKI). The Certificate Policy for administering PKI in Illinois is being adopted by the Illinois Department of Central Management Services, with various State agencies acting as local registration authorities to issue digital certificates (secured through Entrust Technologies, Inc.), and those agencies also administering the servers that authorize access into particular electronic applications based upon which holders of digital certificates are approved to make use of each application. Similarly, at the federal level, the X.509 Certificate Policy for administering PKI is being developed by the Federal Bridge Certification Authority to allow for interoperability of PKI with various federal agency domains. It is anticipated that Illinois and various other States with PKI will adopt a Certificate Policy and PKI procedures that are compatible with those of the Federal Bridge Certification Authority. The procedure for renewal statements called for by USEPA should be no more burdensome than renewal of digital certificates under the PKI Certificate Policy. The frequency for electronic reporting renewal statements needs to take into account the fact that under a number of environmental reporting programs the frequency of report submittal will only be annually. Consequently, the submitter should not have to go through the steps of a renewal process every time they are ready to submit such an annual report.

Whenever possible, the process of completing the agreements and renewal statements called for by USEPA should be handled electronically, with appropriate electronic signatures, rather than having to be signed on paper. The burden on both the submitter and the receiving

agency to conduct electronic reporting is substantially increased whenever sets of paper documents related to the reporting have to be manually filed and maintained.

Furthermore, the burden on submitters and the receiving agency would be significantly and unnecessarily increased by requiring an additional certification statement to be signed whenever the signature holder surrenders the signature. The obligation of the original signature agreement upon the signature holder to notify the receiving agency as soon as he or she no longer represents the regulated entity for which electronic reports are being submitted, as well as the content of the certification statement electronically signed each time a report is submitted, should be adequate assurances that the signature holder properly utilizes their electronic signature. Having to secure and archive an additional certification statement from former employees of a regulated entity would require considerable additional personnel time and record maintenance efforts.

4. Electronic Signature/Certification Scenario

Issue - USEPA proposes to require that an electronic document receiving system must validate only electronic signatures that have been affixed after: (1) the submitter has scrolled through on-screen pages that present all the data to be certified in a familiar, human-readable format; (2) the screen displays a certification statement, just above the place on the screen where the submitter is prompted to initiate the signing process, that is similar or identical to the certifying language required on the corresponding paper submissions of the report; and (3) the submitter has seen a warning, prominently displayed together with the certification statement, that by initiating the signing process the submitter agrees that he or she is using the signature in compliance with the signature agreement that was signed when the signature device was issued.

Comment - A requirement that the submitter must scroll through all of the data on-screen as part of the scenario to be completed just before the electronic signature is affixed to the report would be unduly cumbersome for lengthy reports. Electronic documents covering such matters as annual hazardous waste reports, annual air emissions reports and even reports submitted on a more frequent basis, such as DMRs for complex manufacturing facilities, can encompass up to thousands of screens of analytic data. This data would presumably already have been reviewed as part of the data entry process. Signature of the certification statement would attest to the accuracy and completeness of the data. Therefore, an additional requirement for a final scroll through of all of the data on-screen would be redundant and unnecessary, as well being overly burdensome for lengthy reports.

Issue - Once the electronic signature is affixed and the electronic document submitted, USEPA is proposing that an automatic acknowledgment be sent to the submitter's computer and to the regulated entity responsible for the report via an address that does not share the same access control as the system from which the electronic report was signed and sent. The

automatic acknowledgment would confirm that the report had been received and any affixed electronic signature validated, along with specifying the time and date of receipt.

Comment - This requirement would mean that the receiving agency would be obligated to maintain records of two separate sets of addresses associated with each electronic report and to send out two acknowledgments for each received report, even if this means that one has to be sent via the United States Postal Service. This would be a substantial additional burden of record maintenance and personnel time on the receiving agency, since at the present time there is no requirement for agencies to acknowledge a submission as received. Reporting entities that presently do want verification of submission receipt generally use certified mail for that purpose.

V. The Central Data Exchange (CDX)

A. What Is EPA's Concept of the CDX? - p. 46179

Issue - Specifications for a central data exchange ("CDX") to serve as USEPA's primary gateway for electronic documents received by USEPA are currently being developed by USEPA's Office of Environmental Information. Regulated entities reporting directly to USEPA would use the CDX for electronic reporting applications. CDX may also provide the platform for State exchanges of data with USEPA to implement administrative arrangements for data sharing. The option to allow a State to choose to use CDX as a gateway for electronic data submissions by their regulated entities under USEPA authorized/approved State programs, as an alternative to the State building their own system, is additionally being considered by USEPA.

Comment - Illinois EPA generally supports the concept of the CDX and encourages USEPA to provide the option of allowing regulated entities, in States where primacy to administer a federal environmental program has been delegated to that State, to submit their electronic reports directly into USEPA's CDX. This option would be particularly useful for regulated entities which have facilities subject to reporting under federal environmental programs in multiple States.

B. What Are the CDX Building Blocks? - p. 46180

3. The CDX Architecture

Issue - To provide security for data exchanges, CDX will use a protocol that encrypts the files being exchanged between a "client" personal computer ("PC") and the CDX server while the files travel through the network. Access to the private key that generates the digital signature will be password protected. Current plans further call for the CDX client software to be "localized" to the particular PC on which it is installed, thus preventing access to this software from other PCs connected to it via a network.

Comment - While the described plans for CDX architecture are only tentative at this point and are not part of the contemplated requirements described for design of State electronic reporting systems, USEPA should be cautious not to exclude the use of new, advanced technological solutions for managing digital signatures. As a particular example, USEPA refers to plans for the CDX client software to be localized to the particular PC on which it is installed. In Illinois, the State has contracted for use of digital certificates secured through Entrust Technologies, Inc. Future design of an electronic reporting system for the Illinois EPA may well include application of Entrust's TruePass software which employs "zero-footprint" encryption and digital signature verification. Client software does not need to be installed or configured on a user's computer to deliver the certificate-based security features designed into TruePass. Further information on Entrust TruePass software can be found on the Internet at <http://www.entrust.com/truepass/index.htm>.

40 CFR PART 3 – [NEW] ELECTRONIC REPORTING; ELECTRONIC RECORDS

Subpart C – Electronic Recordkeeping under EPA Programs - p. 46190

Sec. 3.2000 What are the criteria for acceptable electronic document receiving systems?

Issue - The proposed rule at 40 CFR 3.2000(e)(1)(i) would provide that, as part of the electronic signature/certification scenario, the person who is electronically signing the document first be provided with "an opportunity to review all of the data to be transmitted in an on-screen visual format that clearly associates the descriptions or labeling of the information being requested with the signatory's response and which format is identical or nearly identical to the visual format in which a corresponding paper document would be submitted".

Comment - Requiring that the electronic document be identical or nearly identical to the visual format of the corresponding paper document unduly limits the receiving agency's ability to design an electronic document receiving system that efficiently and effectively utilizes the advantages offered by use of an on-line Web-based form. Web designers have recognized for a long time that simply converting the layout and content of paper documents to Web-based display is generally not the best way to make use of the features that can be provided in an on-line application. Use of helpful icons and hypertext links are a couple of the many features that can be incorporated when redesigning paper content for ease of use through a Web browser. In the case of paper reporting forms, the layout often is not conducive to simply recreation in the same format for on-line use. As just one example, the horizontal extent and font size of a paper form's layout may necessitate extensive horizontal scrolling when the same form is viewed through a Web browser. Obviously, it is easier for the user to complete the form and to understand the form's content if a clearer on-screen layout is designed that does not require such scrolling.

**40 CFR PART 142 – NATIONAL PRIMARY DRINKING WATER REGULATIONS
IMPLEMENTATION**

Sec. 142.10 Requirements for a determination of primary enforcement responsibility.
- p. 46193

Issue - The proposed rule at 40 CFR 142.10(h) would, in the case of electronic reporting implementation pertaining to the Safe Drinking Water Act, require that States seeking approval for their electronic reporting systems first adopt regulations consistent with USEPA's electronic reporting requirements at 40 CFR Part 3. It may not be necessary under State law for all States that wish to develop electronic reporting systems for drinking water reports to adopt the content of 40 CFR Part 3 as formal State regulations. In some States, existing law may allow the State to directly apply such federal requirements to the regulated entities reporting to the State without further rulemaking. Additionally, use of signature agreements and renewal statements may provide sufficient basis under State law for the State agency to implement electronic reporting with participating members of the regulated entities, given that the basic monitoring and reporting requirements applicable to those entities would already be covered by existing State regulations.